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Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Attorney Docket No.: 016866-008200US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Edward J. Gavin, et al.

Application No.: 10/084,587

Filed: February 25, 2002

For: METHOD FOR ANALYZING MASS

SPECTRA

Customer No.: 20350

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Attached is a copy of the Notice Regarding Benefit/Priority Claim(s) and a copy of the Official Filing Receipt as received from the Patent and Trademark Office in the abovenoted application for which issuance of a corrected filing receipt is respectfully requested.

We filed an Amendment on July 13, 2004 in order to correct the priority claim as instructed in the Notice Regarding Benefit/Priority Claim(s). A copy of the amendment is attached and a Supplemental Application Data Sheet.

Please correct and issue a new Official Filing Receipt showing the priority data as claimed by applicant.

Confirmation No.: 6008

Examiner: Tung S. Lau

Art Unit: 2863

RESPONSE TO NOTICE REGARDING BENEFIT/PRIORITY CLAIMED AND REQUEST FOR CORRECTED FILING

RECEIPT

Attorney Docket No.: 016866-008200US PATENT

Application No.: 10/084,587

Page 2

Applicants believe no fee is due for the filing of these papers, however, the Commissioner is authorized to charge any additional fees or credit overpayment to undersigned's Deposit Account No. 20-1430.

Respectfully submitted,

Patrick R. Jewik Reg. No. 40,456

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PRJ:asb 60442390 v1



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

APPLICATION NUMBER

FILING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE

10/084,587

02/25/2002

Edward J. Gavin

016866-008200US

20350

TOWNSEND AND TOWNSEND AND CREW, LIP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834



CONFIRMATION NO. 6008

OC000000011018180



Date Mailed: 10/09/2003

Notice Regarding Benefit/Priority Claim(s)

Improper Benefit Claim(s) to Prior-Filed Nonprovisional Application(s)

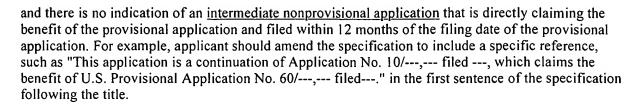
The benefit claim(s) to prior-filed nonprovisional application(s) is improper because there is no specific reference for each prior-filed application that includes: (1) the identification of the prior-filed application by application number, or international application number and international filing date; and (2) a clear indication the <u>relationship</u> (i.e., continuation, divisional, or continuation-in-part) of the nonprovisional applications. For example, applicant should amend the specification to include a specific reference, such as "This application is a continuation of Application No. 10/---,--- filed ----." in the first sentence of the specification following the title.

Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed application(s) as required by 37 CFR 1.78. A proper relationship includes an identification of each nonprovisional application as a continuation, divisional or continuation-in-part application of the immediate prior-filed nonprovisional application for which a benefit is claimed under 37 CFR 1.78 in order to establish copendency throughout the entire chain of prior-filed applications. The specific reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed. See 37 CFR 1.78(a).

Improper Benefit Claim(s) to Prior-Filed Nonprovisional Application(s)

The benefit claim(s) to prior-filed provisional application(s) is improper because the instant application was not filed within twelve (12) months from the filing date of the provisional application,



Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed applications (including an indication of any intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed with 12 months of the filing date of the provisional application) as required by 37 CFR 1.78. The required reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed during the pendency of the instant application.

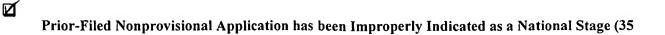
Improper Priority Claim(s) to Prior-Filed Foreign Application(s)

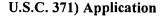
The instant application was not filed within twelve (12) months from the filing date of the prior-filed foreign application, and there is no benefit claim to an intermediate nonprovisional application filed within 12 months of the filing date of the foreign application. Applicant should review each priority claim submitted and, if appropriate, provide the proper reference to any intermediate nonprovisional application filed within 12 months of the filing date of the foreign application in compliance with 37 CFR 1.78, or delete the priority claim. The required reference to an intermediate nonprovisional application must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for the benefit claim to an intermediate nonprovisional application must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed.

■ Benefit Claims to More Than 400 Prior-Filed Applications

The Office's automated system to record and capture benefit claims is only capable of recording benefit claims for 400 prior-filed applications. Therefore, the Office is unable to generate a filing receipt containing benefit claims for more than 400 prior-filed applications even though applicant is entitled to submit benefit claims for more than 400 prior-filed applications. Accordingly, applicant should not request a corrected filing receipt to include benefit claims for more than 400 prior-filed applications.





Applicant submitted a benefit claim to a prior-filed nonprovisional application and improperly indicated that the prior-filed application is a national stage application under 35 U.S.C. 371. The Office's records show that the prior-filed application is an application filed under 35 U.S.C. 111(a). The Office has entered the benefit claim to the prior-filed application as a benefit claim to an application filed under 35 U.S.C. 111(a). Any request for a corrected filing receipt to include the indication that the prior-filed application is a national stage application will not be granted unless applicant supplies evidence that the prior application was in fact a national stage application. Accordingly, applicant should not submit such request without such evidence. Applicant should submit an amendment (or an application data sheet (ADS) if the benefit claim was submitted in an ADS) to delete the indication that the prior-filed application is a national stage application.

For more information and examples on benefit claims, please see <u>Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. 119(e), 120, 121, and 365(c)</u>, 1268 <u>Off. Gaz. Pat. Office</u> 89 (March 18, 2003), which is available on the USPTO website at http://www.uspto.gov/web/offices/com/sol/og/2003/week11/patbene.htm, and the Manual of Patent Examining Procedure (MPEP) §§ 201.11 and 201.14.

PART 2 - COPY TO BE RETURNED WITH RESPONSE



United States Patent and Trademark Office

016866-008200US PRJ

COMMISSIONER FOR PATENTS

UNITED STATES PATENT AND TRADEMARK OFFICE WASHINGTON, D.C. 20231

www.uspto.gov

APPLICATION NUMBER FILING DATE GRP ART UNIT FIL FEE REC'D ATTY.DOCKET.NO DRAWINGS TOT CLAIMS IND CLAIMS

10/084,587 02/25/2002 2857 600 E 1686610 39 2

20350 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 CONFIRMATION NO. 6008
UPDATED FILING RECEIPT

OC0000000008409667

Date Mailed: 07/08/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Edward J. Gavin, San Jose, CA; Leonid Braginsky, Newton, MA; William E. Rich, Redwood Shores, CA; Eric T. Fung, Cupertino, CA; George L. Wright JR., Virginia Beach, VA;

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted 03/21/2002

Projected Publication Date: 08/28/2003

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Method for analyzing mass spectra

Preliminary Class

702

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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NOT GRANTED

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Application Data Sheet

Application Information

Application number::	<u>10/084,587</u>

Filing Date:: 02/25/02

Application Type:: Regular

Subject Matter:: Utility

Suggested classification::

Suggested Group Art Unit::

CD-ROM or CD-R??::

Number of CD disks::

Number of copies of CDs::

Sequence Submission::

Computer Readable Form (CRF)?::

Number of copies of CRF::

Title:: METHOD FOR ANALYZING MASS SPECTRA

Attorney Docket Number:: 016866-008200US

Request for Early Publication:: No

Request for Non-Publication:: No

Suggested Drawing Figure:: 5

Total Drawing Sheets:: 10

Small Entity?:: Yes

Latin name::

Variety denomination name::

Petition included?:: No

Petition Type::

Licensed US Govt. Agency::

Contract or Grant Numbers One::

Secrecy Order in Parent Appl.:: No

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Page 3 Supplemental 10/084,587 2/25/02 3/11/05

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Correspondence Information

Correspondence Customer Number:: 20350

Representative Information

Representative Customer Number:: 20350

Domestic Priority Information

Application:: Continuity Type:: Parent Application:: Parent Filing Date::

This Application National Stage of PCT/US01/44972 11/15/01

Continuation of

10/084,587 Non-Provisional of 60/254,746 12/11/00

Page 4 Supplemental 10/084,587 2/25/02 3/11/05

10/084,587

Non-Provisional of

60/249,835

11/16/00

Foreign Priority Information

Country::

Application number::

Filing Date::

Assignee Information

Assignee Name::

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State or Province of mailing address::

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Country of mailing address::

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Postal or Zip Code of mailing address:: 94555

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<u>PATENT</u>

Attorney Docket No.: 016866-008200US

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

on 7-13-24

TOWNSEND and NOWNSEND and CREW LLP

By: Kua Kaisen



COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Edward J. Gavin, et al.

Application No.: 10/084,587

Filed: February 25, 2002

For: METHOD FOR ANALYZING

MASS SPECTRA

Customer No.: 20350

Confirmation No.

Examiner: Tung S. Lau

Technology Center/Art Unit: 2863

AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed January 14, 2004, please enter the

following amendments and remarks:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

Amendments to the Specification:

Please replace the paragraph at page 1, line 5 of the specification with the following amended paragraph:

This application is a national stage continuation application of International Application No. PCT/US01/44972, filed November 15, 2001, which claims priority to U.S. Provisional Patent Application Nos. 60/249,835 filed November 16, 2000 and 60/254,746 filed December 11, 2000. The above applications are herein incorporated by reference in their entirety for all purposes.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

- Claim 1. (original) A method that analyzes mass spectra using a digital computer, the method comprising:
- a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio, and is created using a laser desorption ionization process; and
- b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process.
- Claim 2. (original) The method of claim 1 wherein the mass spectra are selected from the group consisting of MALDI spectra, surface enhanced laser desorption/ionization spectra, and electrospray ionization spectra.
- Claim 3. (original) The method of claim 1 wherein the class set consists of exactly two classes.
- Claim 4. (original) The method of claim 1 wherein the samples comprise biomolecules selected from the group consisting of polypeptides and nucleic acids.

- Claim 5. (original) The method of claim 1 wherein the samples are derived from a eukaryote, a prokaryote or a virus.
- Claim 6. (original) The method of claim 1 wherein the different biological statuses comprise a normal status and a pathological status.
- Claim 7. (original) The method of claim 1 where the different biological statuses comprise un-diseased, low grade cancer and high grade cancer.
- Claim 8. (original) The method of claim 1 wherein the different biological statuses comprise a drug treated state and a non-drug treated state.
- Claim 9. (original) The method of claim 1 wherein the different biological statuses comprise a drug-responder state and a drug-non-responder state.
- Claim 10. (original) The method of claim 1 wherein the different biological statuses comprise a toxic state and a non-toxic state.
- Claim 11. (original) The method of claim 10 wherein the toxic state results from exposure to a drug.
- Claim 12. (original) The method of claim 1 wherein the data set is a known data set, and each sample is assigned to one of the classes before the data set is entered into the digital computer.
- Claim 13. (original) The method of claim 1 wherein forming the classification model comprises using pre-existing marker data to form the classification model.
- Claim 14. (original) The method of claim 1 wherein the data set is formed by:

detecting signals in the mass spectra, each mass spectrum comprising data representing signal strength as a function of mass-to-charge ratio;

clustering the signals having similar mass-to-charge ratios into signal clusters; selecting signal clusters having at least a predetermined number of signals with signal intensities above a predetermined value;

identifying the mass-to-charge ratios corresponding to the selected signal clusters; and

forming the data set using signal intensities at the identified mass-to-charge ratios.

- Claim 15. (original) The method of claim 1 wherein forming the classification model comprises at least one of identifying features that discriminate between the different biological statuses, and learning.
- Claim 16. (original) The method of claim 1 wherein the classification process comprises a neural network analysis.
- Claim 17. (original) The method of claim 1 further comprising:
- c) interrogating the classification model to determine if one or more features discriminate between the different biological statuses.
- Claim 18. (original) The method of claim 1 further comprising:
 - c) repeating a) and b) using a larger plurality of samples.
- Claim 19. (original) The method of claim 1 wherein the classification process is a cluster analysis.
- Claim 20. (original) The method of claim 1 further comprising forming the data set, wherein forming the data set comprises obtaining raw data from the mass spectra and then preprocessing the raw mass spectra data to form the data set.

- Claim 21. (original) The method of claim 1 wherein the different classes are selected from exposure to a drug, exposure to one of a class of drugs and lack of exposure to a drug or one of a class of drugs.
- Claim 22. (original) The method of claim 1 wherein the each mass spectrum comprises data representing signal strength as a function mass-to-charge ratio or a value derived from mass-to-charge ratio.
- Claim 23. (original) A method for classifying an unknown sample into a class characterized by a biological status using a digital computer, the method comprising:
- a) entering data obtained from a mass spectrum of the unknown sample into a digital computer; and
- b) processing the mass spectrum data using the classification model formed by the method of claim 1 to classify the unknown sample in a class characterized by a biological status.
- Claim 23. The method of claim 23 wherein the class is characterized by a disease status.
- Claim 24. (original) The method of claim 23 wherein the different biological statuses comprise un-diseased, low grade cancer and high grade cancer.
- Claim 25. (original) The method of claim 23 wherein the class is characterized by exposure to a drug of one of a class of drugs.
- Claim 26. (original) The method of claim 23 wherein the class is characterized by response to a drug.
- Claim 27. (original) The method of claim 23 wherein the class is characterized by a toxicity status.

- Claim 28. (original) A method for estimating the likelihood that an unknown sample is accurately classified as belonging to a class characterized by a biological status using a digital computer, the method comprising:
- a) entering data obtained from a mass spectrum of the unknown sample into a digital computer; and
- b) processing the mass spectrum data using the classification model formed by the method of claim 1 to estimate the likelihood that the unknown sample is accurately classified into a class characterized by a biological status.
- Claim 29. (original) A computer readable medium comprising:
- a) code for entering data obtained from a mass spectrum of an unknown sample into a digital computer; and
- b) code for processing the mass spectrum data using the classification model formed by the method of claim 1 to classify the unknown sample in a class characterized by a biological status.
- Claim 30. (original) A system comprising:
 - a gas phase ion spectrometer;
- a digital computer adapted to process data from the gas phase ion spectrometer; and the computer readable medium of claim 29 in operative association with the digital computer.
- Claim 31. (original) The system of claim 30 wherein the gas phase ion spectrometer is adapted to perform a laser desorption ionization process.
- Claim 32. (original) A computer readable medium comprising:
- a) code for entering data obtained from a mass spectrum of an unknown sample into a digital computer; and

- b) code for processing the mass spectrum data using the classification model formed by the method of claim 1 to estimate the likelihood that the unknown sample is accurately classified into a class characterized by a biological status.
- Claim 33. (original) A system comprising:
 - a gas phase ion spectrometer;
- a digital computer adapted to process data from the gas phase ion spectrometer; and the computer readable medium of claim 32 in operative association with the digital computer.
- Claim 34. (original) The system of claim 33 wherein the gas phase ion spectrometer is adapted to perform a laser desorption ionization process.
- Claim 35. (original) A computer readable medium comprising:
- a) code for entering data derived from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set of two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio or a value derived from mass-to-charge ratio or time-of-flight, and is created using a laser desorption ionization process; and
- b) code for forming a classification model using a classification process, wherein the classification model discriminates between the classes in the class set.
- Claim 36. (original) The computer readable medium of claim 35 wherein the classification process comprises a neural network analysis.
- Claim 37. (original) A system comprising:
 - a gas phase ion spectrometer;
 - a digital computer adapted to process data from the gas phase ion spectrometer; and

the computer readable medium of claim 35 in operative association with the digital computer.

- Claim 38. (original) The system of claim 37 wherein the gas phase ion spectrometer is adapted to perform a laser desorption ionization process.
- Claim 39. (previously presented) The method of claim 1 wherein the mass spectra are derived from a surface enhanced laser desorption/ionization process using a substrate comprising an affinity material, wherein the affinity material comprises antibodies.
- Claim 40. (previously presented) A method for classifying an unknown sample into a class characterized by a biological status using a digital computer, the method comprising:
- a) entering data obtained from a mass spectrum of the unknown sample into a digital computer, wherein the mass spectrum is derived from a surface enhanced laser desorption/ionization process using a substrate comprising an affinity material, wherein the affinity material comprises antibodies; and
- b) processing the mass spectrum data using the classification model formed by the method of claim 1 to classify the unknown sample in a class characterized by a biological status.

REMARKS/ARGUMENTS

This Amendment is responsive to the Office Action mailed on January 14, 2004.

Prior to this Amendment, claims 1-40 were pending and subject to examination.

In this Amendment, a duplicate claim 23 is canceled. No claims are amended and no claims are added. Accordingly, claims 1-40 are pending and subject to examination.

At page 6 of the Office Action, the Examiner indicates that claims 16, 20, and 36 would be allowable if rewritten into independent form. The Examiner is thanked for this indication of allowable subject matter.

In the Office Action, claims 1-40 are provisionally rejected under the doctrine of obviousness double patenting.

Applicants note this rejection, and request that this rejection be held in abeyance until the claims are otherwise allowable.

Claims 1-15, 17-19, 21-35, and 37-40 are rejected as anticipated by Hillenkamp (U.S. Patent No. 6,558,902). This rejection is traversed.

Hillenkamp does not anticipate the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Here, Hillenkamp fails to teach or suggest a method including, *inter alia*, "entering into a digital computer a data set obtained from mass spectra" as recited in independent claim 1. Hillenkamp also fails to teach or suggest a computer readable medium comprising, *inter alia*, "code for entering data derived from mass spectra from a plurality of samples" as recited in independent claim 35. Hillenkamp mentions an infrared matrix-assisted laser desorption/ionization mass spectrometric analysis of macromolecules. Hillenkamp does not teach or suggest that his data is to be analyzed with a digital computer. In fact, Hillenkamp fails to mention the word "computer" at all, let alone the particular computer implemented method of claim 1 and the computer readable medium of claim 35. Since Hillenkamp fails to teach each and every limitation of independent claims 1 and 35, Hillenkamp

fails to anticipate the pending claims. Accordingly, withdrawal of the anticipation rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Patrick R. Jewik Reg. No. 40,456

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PRJ:prj 60246015 v1